Pharmaceutical Operational Excellence– A suitable concept for Kenya?

[1]Friedli, Thomas; [2]Lembke, Nikolaus; [3]Bellm, Daniel
[1]Prof. of Production Management, Vice Director Institute of Technology Management, University of St. Gallen, Switzerland
[2]Research Associate at the Institute of Technology Management, University of St.Gallen, Switzerland
[3]Research Associate at the Institute of Technology Management, University of St.Gallen, Switzerland

Key words: Operational Excellence, Pharmaceutical Industry, Kenya

Introduction

The pharmaceutical environment

The global pharmaceutical industry currently faces a great upheaval that poses severe challenges to organizations of all sizes. Companies which were blessed with success until yesterday are now confronted with patent expirations, R&D pipelines running dry and considerable overcapacities. A constantly increasing competition and complexity within pharmaceutical manufacturing make pharma a tough business [1].

The current situation which pharma endures came, however, not out of the blue. Moreover, especially large research driven and generic manufacturers, working on margins´ edge, searched for and developed their own defence mechanisms to sustain in global business. One of the most promising approaches to improve a company´s situation that hit pharma agenda at the turn of the century is the relentless effort to achieve operational excellence (OPEX).

Operational excellence defined

Operational excellence in particular "[…] constitutes the continuous pursuit of improvement of a production plant in all dimensions. Improvement is measured by balanced performance metrics comprising efficiency and effectiveness, thus providing a mutual basis for an improvement evaluation". [2] The philosophy of operational excellence traces back to approaches of World Class Manufacturing [3], or even earlier to all those well-known Japanese manufacturing concepts, most impressively publicized in conjunction with the Toyota Production System [4, 5]. Based on the work of Cua et al. [6], the Institute of Technology Management of the University of St. Gallen, Switzerland, developed a framework for the structured discussion of operational excellence in a pharmaceutical context which was officially published [7].

The framework includes three distinctive dimensions, i.e. a (1) technical and a (2) social sub-system, and (3) the basic elements. The technical sub-system builds on the three manufacturing improvement programs shortened by the acronyms Total Productive Maintenance (TPM), Total Quality Management (TQM), and Just-in-Time (JIT). The social sub-system is termed as Effective Management System (EMS) and emphasizes the value of creating a working atmosphere for employees so as to allow organizational improvement. Forming the basis of the framework, it highlights the significance of any organization´s people. Basic elements have their validity for all three technical programs. The three dimensions, covering the theoretical dimensions of a pharmaceutical manufacturing site, reinforce each other and reflect a system in which all elements are directly and indirectly influenced by interventions or the adjustment of single elements [2].

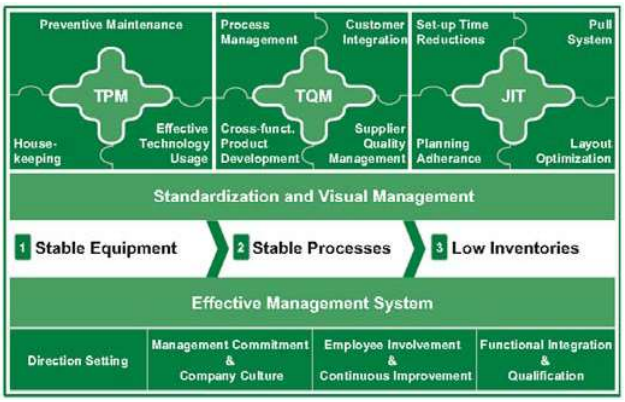

Figure 1: *The St. Gallen model for operational excellence* [2]

TPM aims to maximize the effectiveness of used equipment in production, all at moderate costs. Therefore, the main focus of TPM optimization does not lie in short-term reduction of costs for equipment and maintenance; rather, TPM is concerned with the optimal support of production processes based on stable and reliable equipment. Thus, TPM provides the basis for improvements in efficiency. TPM does not only focus on technical aspects such as equipment reliability, but also involves engaging all employees in maintenance-related activities. TQM is a holistic quality philosophy involving all employees from top management (role model) to the shop-floor with the objective of continuously improving the quality of products and processes. Activities are based on the assumption that costs for correcting quality activities are higher than for preventive quality activities like process management, customer integration or an adequate supplier management. JIT is a crucial element to increase flexibility by avoiding excessive inventories. It provides the customer with goods in the right quality and quantity when he needs

it. Furthermore, focused on manufacturing site´s internal processes, it supports the continuous reduction and ultimate elimination of waste like inventory and overproduction [8].

The basic elements 'Standardization' and 'Visual Management' are crucial to realizing the full potential of TPM, TQM, and JIT. Methods like 5S and Visual Management are not limited to the production and shop-floor area, but can equally be applied in the laboratories and offices.

EMS represents the social aspect of operational excellence and emphasizes the importance of top management commitment, company culture and a broad employee involvement in order to realize a sustainable success of any operational excellence initiative [8].

The evolution of operational excellence in pharma

Over the last decade the role and perception of pharmaceutical operational excellence has changed significantly. Whereas single and stand-alone approaches of operational excellence were first introduced by large companies, they realized quickly that a mere copy and paste from successful automotive organizations would not fit the pharmaceutical requirements in the long run [9]. Today, almost all pharmaceutical manufacturers apply selected concepts and approaches from the OPEX tool box in order to increase their efficiency [10]. However, the evolution of operational excellence in pharma showed that reaching operational excellence is far more than solely applying tools. Especially large research driven organizations started their transformation with broad trainings of their entire workforce. The provision of basic trainings to drive efficiency and effectiveness had several advantages: first, training people in tools like problem solving or process mapping increase the know-how and awareness of employees for their daily challenges within operations. Secondly, providing large scale training is a signal by management that starting the transformation towards operational excellence is more than just fad – it is the ignition of a changing mindset to drive responsibility and empowerment of people. Thirdly, these basic trainings equip people on shop-floor with the skills to create and maintain a pharmaceutical environment which meets the basic requirements of cGMP1.

OPEX in Kenya – it is about people

The philosophy of operational excellence is suitable for all cultures [5]. Besides, transforming a manufacturing site to an operationally excellent environment is neither dependent on state-of-the-art equipment [11] nor is it restricted to a certain industry, product mix or business model [12]. Nevertheless, prevailing manufacturing challenges in Kenya as described by UNIDO [13] might deter some managers from exuberant optimism and, rather, lead them to treat operational excellence with reserve.

In 2013, in a joint cooperation with UNIDO, a research team of the University of St. Gallen visited several manufacturing sites in Nairobi, Kenya. Though the companies belong to some of the most advanced pharma companies of the country, they represented varying levels of pharmaceutical manufacturing capabilities. The research team held several interviews with the site leadership teams and people on shop-floor in order to become familiar with the Kenyan manufacturing environment.

In general, the findings support Liker´s proposition [5] that the concept of operational excellence is applicable everywhere. More precisely, every system requires stability which is all the more demanding to realize in a volatile environment such as Sub-Saharan Africa. Following the lessons from the St. Gallen model for operational excellence, the first step for Kenyan pharmaceutical companies towards OPEX is recommended as a broad engagement with TPM. Introduced top-down and supported by the site´s entire leadership team, a training program needs to be set up to train people in housekeeping approaches. In such cases 5S is not limited to the shop-floor but embraces all facets of a manufacturing site, e.g. storage, utilities, laboratories, etc. People need to be encouraged and empowered by management to strive for improvement and pharmaceutical cleanliness of their workplace which includes the meticulous care of all equipment time and again. Moreover, management has to actively involve people from all hierarchies in improving the site´s operations. Since it is the people in areas like dispensing, tableting, packaging, QA/QC or at the storage etc. who daily work in their processes, who are valuable experts for the company, and who are the ones who produce quality, management has to listen to their opinions and suggestions for improvement. To achieve this, people need to be encouraged and managers have to follow a long-term strategy in order to realize such potential.

Conclusion

As the pharmaceutical industry is facing increasing challenges, like a rising complexity, the time has come to realize the potential of sustainably implementing OPEX. Because of the complex and interconnected nature of integrated production systems, adjustments of one sub-system affect all of the other sub-systems. Starting with TPM and then TQM will lead to the needed stability to also strive for the elimination of all kinds of waste (addressing JIT). One of the most important steps which have been taken in the previous years is an expansion of measuring activities and the use of tools such as Statistical Process Control. The knowledge which can be derived from precise measuring is essential in terms of quality and fosters a science of manufacturing. According to Ishikawa [15] data should not be collected to provide the basis for nice figures but to create a basis for action and the development of processes. Collecting the right data and using it as an objective performance indicator in a continuous improvement process will prove to be highly beneficial to pharmaceutical companies [14].

[1] *See Friedli et al. [14] for an overview of the most important tools and their application in pharmaceutical operational excellence.*

References

1. Friedli, T. and Bellm, D. (2013a), "A Look to the Environment and the Impact on OPEX", in Friedli, T., Basu, P., Bellm, D. and Werani, J. (Eds.), Leading Pharmaceutical Operational Excellence, Springer Berlin Heidelberg, Berlin, Heidelberg, pp. 77–321.
2. Friedli, T. and Bellm, D. (2013b), "OPEX: A Definition", in Friedli, T., Basu, P., Bellm, D. and Werani, J. (Eds.), Leading Pharmaceutical Operational Excellence, Springer Berlin Heidelberg, Berlin, Heidelberg, pp. 7–58.
3. Schonberger, R. (1986), World class manufacturing: The lessons of simplicity applied, Free Press; Collier Macmillan, New York, London.
4. Womack, J.P., Jones, D.T. and Roos, D. (1990), The Machine that changed the world, Maxwell Macmillan International, New York.
5. Liker, J.K. (2004), The Toyota way: 14 management principles from the world's greatest manufacturer, McGraw-Hill, New York.
6. Cua, K.O., McKone, K.E. and Schroeder, R.G. (2001), "Relationships between implementation of TQM, JIT, and TPM and manufacturing performance", Journal of Operations Management, Vol. 19 No. 6, pp. 675–694.
7. Friedli, T., Kickuth, M., Stieneker, F., Thaler, P. and Werani, J. (Eds.) (2006), Operational excellence in the pharmaceutical industry, ECV - Ed.-Cantor-Verl., Aulendorf (Germany).
8. Friedli, T., Lembke, N., Schneider, U. and Gütter, S. (2013b), "The Current State of Operational Excellence Implementation: 10 Years of Benchmarking", in Friedli, T., Basu, P., Bellm, D. and Werani, J. (Eds.), Leading Pharmaceutical Operational Excellence, Springer Berlin Heidelberg, Berlin, Heidelberg, pp. 35–58.
9. Friedli, T. and Werani, J. (2013), "The History of OPEX in the Pharmaceutical Industry", in Friedli, T., Basu, P., Bellm, D. and Werani, J. (Eds.), Leading Pharmaceutical Operational Excellence, Springer Berlin Heidelberg, Berlin, Heidelberg, pp. 27–34.
10. Werani, J., Bellando-Randone, G. and Goetzfried, M. (2010), "Making Operational Excellence Work - Training and Coaching Supporting Behavioral Change", in Friedli, T., Basu, P.K., Gronauer, T. and Werani, J. (Eds.), The Pathway to Operational Excellence in the Pharmaceutical Industry: Overcoming the internal inertia, Editio Cantor, Aulendorf, pp. 220–240.
11. Krafcik, J.F. (1988), "Triumph of the lean production system", Sloan Management Review, Vol. 30 No. 1, pp. 41–52.
12. Kickuth, M. and Friedli, T. (2006), "The Status of the Pharmaceutical Industry", in Friedli, T., Kickuth, M., Stieneker, F., Thaler, P. and Werani, J. (Eds.), Operational excellence in the pharmaceutical industry, ECV - Ed.-Cantor-Verl., Aulendorf (Germany), pp. 53–81.
13. UNIDO (2010), Pharmaceutical Sector Profile: Kenya.
14. Friedli, T., Mänder, C. and Bellm, D. (2013a), "Matching Problems with Tools", in Friedli, T., Basu, P., Bellm, D. and Werani, J. (Eds.), Leading Pharmaceutical Operational Excellence, Springer Berlin Heidelberg, Berlin, Heidelberg, pp. 285–321.
15. Ishikawa, K. (1985), What is total quality control? The Japanese way, Prentice-Hall, Englewood Cliffs, N.J.